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09/529,217 05/05/00 GUILLOT 1029/00190

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EXAMINER

SOUAYA, J

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/529,217

Applicant(s)
Guillot et al

Examiner
Jehanne Souaya

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 5, 2000
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 is indefinite in the recitation of “the microbial population(s)...” in line 1, as the term lacks proper antecedent basis.

B) Claim 1 is indefinite in the recitation of “the microorganisms” in line 4 as the term lacks proper antecedent basis.

C) Claim 1 is indefinite in the recitation of “able to target” as it is unclear what characteristic this lends to the RNA targeted oligonucleotide probe. Furthermore, it is unclear how a probe “targets” a microbial population. For example, does the term “able to target” refer to specific hybridization to DNA of particular species of microorganism, of any species of microorganism?, or can the term refer to antisense technology?

D) Claim 1 is indefinite in the recitation of “extracting by separation from their target and elution outside...” as it is unclear if elution occurs after extraction of target nucleic acids from cells or if the phrase refers to the elution of nucleic acid without cell lysis. Likewise, the reference to “extracted probes” in the last step makes it unclear as to whether the claim is drawn to a method where the probes have been eluted from intact cells, or if cell lysis has occurred.

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E) Claim 2 is indefinite in the recitation of “said at least one specific probe” as the term lacks proper antecedent basis in that the phrase “at least one specific probe” does not occur in previous recitation.

F) Claim 6 is indefinite in that it is unclear where, in the method of claim 1, the step of extracting the microorganisms from the sample by centrifugation. Furthermore, regarding claim 6, the phrase “notably” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. The metes and bounds of the claim are unclear.

G) Claim 7 is indefinite in the recitation of “said cells” as the claim lacks proper antecedent basis.

H) Claim 10 is indefinite in the recitation of “and preferably” as it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

I) Claim 11 is indefinite in the recitation of “said at least one probe” as the term lacks proper antecedent basis in that the phrase “at least one probe” is not previously recited in a claim from which claim 11 depends.

J) Claim 11 is indefinite in the recitation of “notably” in line 4 as it is unclear whether the limitation(s) following the phrase are part of the claimed invention. The metes and bounds of the claim are unclear. Claim 11 is further indefinite in the recitation of “preferably on the order of ...” in lines 6,7,and 9 as it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

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K) Claim 12 is indefinite in the recitation of “said contacting phase” lacks proper antecedent basis as the term “contacting phase” is not previously recited in a claim from which claim 12 depends.

L) Claim 12 is indefinite as the term “the optimal hybridization temperature” lacks proper antecedent basis.

M) Claim 13 is indefinite as the phrase “said extraction of said at least one probe” as the phrase “extraction of said at least one probe” is not previously recited in a claim from which claim 13 depends. The phrase “the excess and unbound probe” also lacks antecedent basis.

N) Claim 13 is indefinite in the recitation of “notably” in lines 4 and 5 as it is unclear whether the limitation(s) following the phrase are part of the claimed invention. The metes and bounds of the claim are unclear. Regarding claim 13, the phrase “such as” in line 6 renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

O) Claim 13 is indefinite as the phrase “the stringency necessary to the removal” is not grammatically correct. The phrase should read “necessary *for* the removal...”

P) Claim 14 is indefinite as the phrase “denaturation of every all probe” is not grammatically correct. The phrase should read “of *every* probe...”.

Q) Claims 14, 16, 17 is indefinite in the recitation of “notably” as it is unclear whether the limitation(s) following the phrase are part of the claimed invention. The metes and bounds of the claims are unclear.

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R) Regarding claims 17 and 18, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Manz et al (Water Research, vol. 28, pp 1715-1723, 1994), Wagner et al (Systematic and Applied Microbiology, vol. 18, pp 251-264; 1995) and De Los Reyes et al

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(Applied and Environmental Microbiology, vol. 63, pp 1107-1117; 1997) in view of Mobarry et al (Applied and Environmental Microbiology, June 1996, vol. 62, pp 2156-2162).

Manz teaches the in situ characterization of microbial organisms in waste water treatment plants (see abstract). Manz teaches that rRNA probes can be used to identify bacteria using in situ hybridization (see p. 1715, col.2). Manz teaches extracting and harvesting cells from sewage plants (p. 1716, col 2). Manz teaches using both species specific and universal fluorescent rRNA probes (p. 1717, col 1) for in situ hybridization . Manz teaches that cells were fixed prior to in situ hybridization with mixtures of paraformaldehyde and ethanol depending on the type of cell wall structure (gram positive vs. Gram negative bacteria, see p 1717, col. 2). Manz teaches that after hybridization nucleic acid was extracted from cells and that nucleic acid concentrations were determined, followed by immobilization of nucleic acids on nylon membranes and probing with digoxigenin-labeled oligonucleotides.

Wagner teaches in situ identification of ammonia oxidizing bacteria (see abstract). Wagner teaches that 16S rRNA oligonucleotides can be used to detect microbial species. Wagner teaches fixing cells, hybridization using species specific and universal bacterial probes in formamide, washing at 48 deg. C. In a buffer containing NaCl, Tris/HCL, and SDS. and the quantification of probe conferred fluorescence (pp 252-253).

De Los Reyes teaches group specific rRNA hybridization probes to characterize filamentous foaming in activated sludge systems (see abstract). De Los Reyes teaches using fluorescence tagged group specific as well as universal probes S-Univ-1390 and Bact-0338 (see p.

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1108, col 1) in an in situ hybridization method to detect and quantify bacteria (see pp 1108).

Mobarry et al teach phylogenetic probes for analyzing nitrifying bacteria in methods of in situ hybridization (see abstract). Mobarry teaches using probes Nb 1000 and Nso 1225. Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to develop a method of identifying and quantifying bacterial populations in samples for the purpose of diagnosing infectious disease or monitoring contamination for treatment of sludge and wastewater or sewage systems as the state of the art was very high with regard to such at the time the invention was made. As exemplified above, the ordinary artisan would have been taught the following: 1) bacterial populations could be identified and quantitated using in situ hybridization and 2) such methods were carried out using both species specific as well as universal probes (it is noted that in a method of detecting proteobacteria, the ordinary artisan would have been taught the use of specific probes Nso 1225 and Nb 1000, and the use of universal probes S-Univ-1390 and Bact-0338). It is noted that the art does not teach eluting hybridized probes from cells without extracting total microbial DNA, however the claims as written do not make clear this method (from reading the examples in the specification, it appears that this is the preferred method of the instant invention. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Guens*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)). The claims as written encompass extraction of DNA from cells followed by fluorescence detection of bound probes outside cells which is taught by De Los Reyes and Manz. Amending the claims to more clearly point out this method and specifically the

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extraction and elution conditions of step e, page 12 of the specification, could aid in overcoming the rejection of the claims over the cited prior art.

4. No claims are allowable.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Jehanne Souaya
Patent examiner
September 28, 2001

[Signature]
W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
10/1/01